K112565

TRADITIONAL 510(K)

510(k) Summary

For the Novalung® GmbH

NovaPort® One Vascular Access

DEC - 6 2011

I. SUBMITTER/510(k) HOLDER:

Novalung® GmbH
Zukunftspark 1
D-74076 Heilbronn, Germany
Telephone: +49 7131 2706 - 0
Telefax: +49 7131 2706 - 299
FDA Establishment Registration Number: 3004569487

II. CONTACT PERSON

Leann Christman, MEd
Telephone: (734) 995-9089 ext. 232
Fax: (734) 995-0840
Email: lchristman@MC3Corp.com

III. DEVICE NAME

Proprietary Trade Name: NovaPort® One Vascular Access
Common/Usual Name: Percutaneous Cannula and Introducer Set

IV. DEVICE CLASS:

Class II

V. CLASSIFICATION NAME:

Cardiopulmonary bypass vascular catheter, cannula, or tubing Classification regulation: Sec. 870.4210

VI. PRODUCT CODES:

DWF

VII. PREDICATE DEVICES

K052524, Bio-Medicus Multi-Stage Venous Femoral Percutaneous Kit
K024069, One Piece Pediatric Arterial Cannula 7000 Models

VIII. PRODUCT DESCRIPTION

The NovaPort® One Vascular Access cannula with Novalung coating are a wire reinforced, thin walled femoral cannula made of polyurethane. A cone without wire reinforcement allows clamping and serves as transition to a connector. The beveled tip is not a separate piece and is part of the whole cannula body. The NovaPort® one cannulas are inserted percutaneously into

vessels. Insertion depth marks aid in positioning the cannula. They have a beveled tip that is made as part of the PVC body.

The Cannula is intended to be used to cannulate vessels, perfuse vessels or organs and/or connect with accessory extracorporeal equipment. The cannula introducer is intended to facilitate proper insertion and placement of the appropriate sized cannula within the vessel for cardiopulmonary bypass.

All surfaces of the NovaPort® One which come into contact with blood are protected with the Novalung Coating. This coating is a bioactive, stable, biocompatible and non-thrombogenic surface. This coating consists of high molecular weight heparin from pig mucosa bound covalently and ionically to immobilized polypeptides.

NovaPort® one cannula is available in insertion lengths of 90 mm and 140 mm and with outer diameters of 13 F, 15 F, 17 F, 19 F and 21 F. All are supplied sterile with Novalung coated, non-pyrogenic, and are single use.

IX. INDICATIONS OF USE

The NovaPort® One Vascular Access cannula with its associated Introducer Kit is a Novalung coated percutaneous cannula intended to be used to cannulate blood vessels in patients requiring extracorporeal support such as cardiopulmonary bypass. The application of NovaPort® One cannula is limited to limited to < 6 hours.

X. TECHNOLOGICAL CHARACTERISITICS AND SUBSTANTIAL EQUIVALENCE

The NovaPort® One Vascular Access are identical to the predicate devices in terms of intended use, indications for use, levels of attachment, fundamental scientific technology, materials and surgical technique. Based on the information provided herein, the subject NovaPort® One Vascular Access have been demonstrated to be substantially equivalent to the previously cleared Bio-Medicus Multi-Stage Venous Femoral Percutaneous Kit (K052524) and the One Piece Pediatric Arterial Cannula 7000 Models. Please refer to the Table 10-1 for a comparison of the predicates and subject Novaport regarding substantial equivalence.

Further on the indications for use of the Novalung coating of the Novaport One cannula with Novalung coating is the same as with the Bioline coating (K102532) and Novalung sLA (K072362).

XI. PERFORMANCE TESTING

The NovaPort® One Vascular Access was subjected to numerous tests and comparisons to the predicate device: testing included pressure/burst, simulated use, kink resistance, tensile strength, flow characteristics, hemolysis, biocompatibility, and validation testing to coating.

XII. SUMMARY AND CONCLUSIONS

Novalung GmbH makes the claim that the NovaPort® One Vascular Access is substantially equivalent to the cited predicates in terms of intended use, indications for use, fundamental technology, design characteristics, generic materials of construction, and operational characteristics. As shown in Table 10-1 and the discussion above, the differences between the NovaPort® One Vascular Access and cited predicates are minor and raise no new issues of

safety or effectiveness. In addition, comparative testing included in this 510(k) premarket notification demonstrates that the NovaPort® One Vascular Access has performance substantially equivalent to Bio-Medicus Multi-Stage Venous Femoral Percutaneous Kit (K052524) and the One Piece Pediatric Arterial Cannula 7000 Models (K024069). The Novaport One meets design specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Novalung® GmbH
c/o Ms. Leann Christman
MC3, Inc.
3550 West Liberty, Suite 3
Ann Arbor, MI 48103

JAN 12 2012

Re: K112565
NovaPort® One Vascular Access and Introducer Kit
Regulation Number: 21 CFR 870.4210
Regulation Name: Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass
Regulatory Class: Class II
Product Code: DWF
Dated: November 4, 2011
Received: November 8, 2011

Dear Ms. Christman:

This letter corrects our substantially equivalent letter of December 6, 2011

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K112565

Device Name: NovaPort® One Vascular Access

Indications for Use:

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Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112565